

REMARKS

Claims 1, 2, 4, 8, 16, 17, 19, 23-31, 33 and 53 are pending. Claims 1, 2, 8, 16, 24 and 53 are amended to clarify the intended scope of the invention. New dependent Claim 54 has been added to further define Claim 1. Support for the amendments can be found throughout the specification.

Rejection Under 35 U.S.C. §103

Claims 1, 2, 4, 8, 16, 17, 19, 23-31 and 33 stand rejected under 35 U.S.C. §103 as being unpatentable over Belef et al (US Pub. No. 2002/0147496) in view of Pernia et al (US Pat. No. 5,634,945). Applicant respectfully traverses this rejection. The Examiner carries the burden to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). “To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art.” MPEP §2143.03. The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done, “[t]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See also, MPEP §§2144-2144.09.

The Office Action of November 29, 2007 asserts that,

“[t]he Belef reference in paragraph 61, clearly disclose growth factors that are capable of stimulating cellular proliferation and cellular differentiation. Additionally, in paragraph 64, Belef discloses a different embodiment having a bioabsorbable bladder that

overtime the implant is absorbed by the patient's body after sufficient time for the annulus fibrosis to substantially heal. Therefore, if the implant is replaced by the patient's tissue over time, then, the growth factors and the rest of the fill materials (over time) promote the growth of tissue."

Applicant respectfully assert that this argument, stating that because the annulus purportedly heals over time means the bladder enclosed fill material and/or growth factors promote tissue growth is not only unsupported but inaccurate. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co.v. Teleflex*, 127 S. Ct. 1727, 1741, citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006). Further, "[i]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP §2142.

Applicant submitted a Declaration (the "Mac Millan Declaration") pursuant to 37 C.F.R. §1.132 from Dr. Mac Millan, a spine surgeon with over 20 years of experience on June 29, 2007, the contents of which are incorporated herein in their entirety. In the Mac Millan Declaration, Dr. Mac Millan testified that none of the materials disclosed by Belef will promote tissue growth and that the nature of the nonporous bladder disclosed by Belef further indicates that the fill material disclosed by Belef does not promote tissue growth. See Mac Millan Declaration paragraphs 6-9. This testimony from a highly experienced spine surgeon, that is, one of skill in the art, was completely disregarded by the Examiner. Instead, the Examiner has substituted his own argument based solely on the Examiner's opinion. Applicant submits herewith a second Declaration (the "Mac Millan Declaration II") pursuant to 37 C.F.R. §1.132, the entirety of

which is incorporated herein by reference. In the Mac Millan Declaration II, Dr. Mac Millan explains that the late stage cellular differentiation required to promote fibrocartilaginous tissue growth is unaffected by growth factors. (Mac Millan Declaration II at paragraph 6). This testimony by one of skill in the art directly contradicts the unsupported argument in the Office Action that the growth factors disclosed in Belef will promote fibrocartilaginous tissue growth.

Dr. Mac Millan's testimony also contradicts the Office Action's assertion that the healing of the annulus evidences that the growth factors and/or fill material disclosed by Belef promote tissue growth. *See* Mac Millan Declaration II at paragraphs 8-10. Further, Belef itself contradicts the Office Action's argument. Belef at Paragraph 64 states:

“Alternatively, the bladder 12 may facilitate healing of an annulus fibrosis, for example, through which fissures and the like have developed. In addition to the nucleus pulposus removed from the interior region 94, any nucleus pulposus that has leaked through such fissures may be removed. In this embodiment, the bladder 12 is preferably substantially nonporous, thereby containing the nucleus pulposus within the bladder 12 while the annulus fibrosis 92 is given opportunity to heal. Preferably, the bladder 12 is bioabsorbable such that the bladder 12 is substantially absorbed by the patient's body after sufficient time for the annulus fibrosis to substantially heal. Thus, once healed, the patient's spinal disc may be restored to a substantially normal, healthy disc.” (emphasis added).

One of skill in art would question whether the annulus is even capable of healing. Further, even if healing of the annulus did occur, any such healing would result from new annular tissue, and not new tissue that would mimic disc tissue as claimed by Applicant here.

See Mac Millan Declaration II at paragraphs 8-10. A plain reading of the Belef reference itself clearly shows that the fill material is enclosed by a nonporous bladder during any healing of the annulus. Because the fill material is enclosed, the fill material is prevented from interacting with the surrounding tissue and as such could not stimulate any tissue growth. *See* Mac Millan Declaration II at paragraphs 8-10.

In stark contrast, independent Claims 1, 2, 8, 16, 24 and 53 all recite that the tissue promoting material be placed in a porous container. The container must be porous so that the fill material is able to interact with the surrounding tissue. This is a fundamental difference between Applicant's invention and Belef's disclosure. Belef discloses the use of fill material merely as an inert substitute for the disc, whereas Applicant's fill material construct is designed to actually promote and create new tissue in the disc space not merely act as an inert occupier of excavated space. *See* Mac Millan Declaration II at paragraphs 5 and 7. Belef itself offers further support of this glaring difference. Belef teaches that the fill material is selected to prevent vascularization. Belef at paragraph 61. However, without vascularization, one cannot grow new tissue. *See* Mac Millan Declaration II at paragraph 11. Nothing in the Belef reference obviates Applicant's invention. Mac Millan Declaration, paragraph 12.

With respect to the Pernia reference, as with Belef, Pernia itself teaches away from promoting tissue growth. Like Belef, Pernia discloses the use of an inert filler material to simply take up the space previously occupied by the patient's tissue. Pernia discloses the use of human hair. Pernia also states that tissue growth is undesirable and teaches that the hair should not interact with the surrounding tissue. *See* Pernia at Col. 4, ln 6-34. In contrast, Applicant's fill material promotes new tissue growth by interacting with the surrounding tissue.

Belef and Pernia, either alone or in combination, do not teach or suggest all the claim limitations, for instance Belef and Pernia do not teach the use of tissue promoting material placed in a porous container to promote tissue growth that mimic the natural disc. Accordingly, it is respectfully submitted that a *prima facie* case of obviousness of independent claims 1, 2, 8, 16, 24 and 53 has not, and cannot be established by the Belef and Pernia references.

With respect to the specific features noted by the Office Action in the Claims depending from Claims 1, 2, 8, 16 and 24, these issues are not commented on further here because they are presently moot given the above analysis, although Applicant does not acquiesce in the Examiner's position. Furthermore, because dependent claims 4, 17, 19, 23, 25-31, 33 and 54 further define independent claims 1, 2, 8, 16 and 24 respectively, Applicant respectfully submits that these claims are also allowable. See MPEP 2143.03 ("If an independent claim is nonobvious under 35 U.S.C 103, then any claim depending therefrom is nonobvious.").

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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